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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,887	03/31/2001	Sanjay Kumar	KUM-108 US	7559

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EXAMINER
SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,887	KUMAR ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is written in response to applicant's correspondence submitted 8/27/2003. Claims 1-4, 6-8, 15-17, 19-20, 23-24 have been canceled, claims 5, 9-14, 18, 21-22, 25-29 have been withdrawn from consideration, and new claims 30-39 have been added. Claims 30-39 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

35 U.S.C. 101/112 Utility Rejections

35 U.S.C. 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not

be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an

animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 30-39 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific, substantial or a well established utility.

The claimed nucleic acid is not supported by a specific asserted utility because the disclosed use of the nucleic acid is not specific and is generally applicable to any nucleic acid. The specification states that the nucleic acids may be useful as a hybridization probe to complementary molecules in other plants using probe design methods, cloning methods, and clone selection as is well known in the art. The specification teaches on page 22 that an embodiment of the invention includes using the novel sequences as probes to look for the sequences of nucleotides in other plants, animal, and/or microbial systems and the like. The novel sequence of SEQ ID NO: 1 is taught to be used to clone full-length cDNA, genomic DNA, promoter and regulatory sequences. Furthermore, an embodiment of modulating winter dormancy using the novel genes in the plants after transferring these genes using the techniques

such as ballistic mediated transformation. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed.

Further, the claimed nucleic acid is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acids have asserted or identified specific and substantial utilities. The research contemplated by applicants to characterize potential full length genes and furthermore their protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid such that another non-asserted utility would be well established for the compounds.

Response to Arguments:

In applicant's response, they assert that the office has not provided evidence supporting a prima facie case of no specific and substantial credible utility. The applicant's assert that "paragraphs [0052]-[0053], and example 8" clearly establish that the present invention is useful in regulating dormancy in plants, and rebuts the office's rejection that purported "the disclosed use of nucleic acid is not specific and is generally applicable"(pg.6). Furthermore the applicant's believe that "modulating winter dormancy using the novel genes in the plants …"(page 6) provides a specific use of their invention. Additionally, applicants assert that the invention has a substantial utility

in modulating dormancy in plants (referencing paragraphs 10-11) that "can have severe agricultural and economic ramifications if untimely"(pg. 7). Lastly applicant asserts that, although not discussed in the office action, applicants assert that their invention of modulating winter dormancy in tea plants to be a credible one.

Although the examiner acknowledges each of applicant's arguments, the examiner maintains that the utility asserted of modulating winter dormancy in tea plants to lack a specific and substantial utility. The specification as originally filed taught only that when non-dormant, dormant, and forced(GA3) buds are probed for SEQ ID NO:1 there is expression of this sequence in the non-dormant and forced(GA3) buds. The specification does not assert that it is specifically SEQ ID NO:1 that is responsible for the transition to non-dormancy from dormancy. As such the current invention's asserted utility of modulating winter dormancy in tea plants is maintained to be non-specific. In addition, the examiner asserts that the presently claimed utility requires carrying out further research to identify or reasonably confirm a "real world" context of use. As the present specification provides only that the detection of SEQ ID NO:1 in non-dormant, dormant, and forced(GA3), samples is practiced by the applicant and not the over-expression/repression of SEQ ID NO:1 that is directly responsible for the entry into non-dormancy, but instead the application of a plant growth regulator, gibberellic acid(GA3) that is responsible for the buds entry into non-dormancy, SEQ ID NO:1 does not represent a substantial utility. SEQ ID NO:1 may or may not be present in non-dormant/dormant buds, but to assert that its mere detection implies its responsibility for the transition requires further research to substantiate. No evidence has been provided that reveals that SEQ ID NO:1 is solely responsible for modulating winter dormancy in tea plants, as a multitude of other events that occur when GA3 is administered could account for the modulation. "The applicant is reminded that once a *prima facie* showing of no specific and substantial utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or printed publication that rebuts the basis or logic of the *prima facie* showing"(Federal Register/Vol.66, No.4, January 5, 2001, *Guidelines for Examination of applicantions for compliance with the utility requirement).*

Claim Rejections - 35 USC § 112

2. Claims 30-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Response to Arguments:

Applicant's traversal of the rejection under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention is acknowledged. Applicant asserts that as they responded to the 101 utility rejection their response to this rejection is incorporated by reference. While applicants "respectfully contend that both rejections are not well founded in the facts of the present case and should be withdrawn"(pg.8), the examiner maintains the utility rejection for her reasons set forth above and as a result maintains her enablement rejection as without a specific and substantial utility, enablement is also lacking.

3. A review of the language of the claim indicates that the claim is drawn to a genus, i.e., any DNA sequence **comprising** the polynucleotide sequence of SEQ ID NO:1.

The search indicates that that SEQ ID NO: 1 is a novel and unobvious sequence. There is a single species explicitly disclosed(a molecule consisting of SEQ ID NO: 1 that is within the scope of the claimed genus).

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses full length genes, splice variants, cDNAs, and genomic DNA that are not further described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO:1 is only a 3' end fragment, of any full length gene or cDNA species. When reviewing a claim that encompasses a widely varying genus, the examiner must evaluate any necessary common attributes or features. In the case of a partial cDNA sequence that is claimed with open language (comprising), the genus of, e.g., "a DNA sequence comprising SEQ ID NO:1," encompasses a variety of subgenera with widely varying attributes. For example, a cDNA's principle attribute would include its coding region. A partial cDNA that did not include a disclosure of any open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed. Further, defining "the" cDNA in functional terms would not suffice in the absence of a disclosure of structural features or elements of a cDNA that would encode a protein having a stated function.

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the specification discloses only a single common structural feature shared by members of the claimed genus i.e., a sequence comprising SEQ ID NO:1. Since the claimed genus encompasses genes yet to be discovered, splice variants, etc., the disclosed structural feature does not "constitute a substantial portion" of the claimed genus. Therefore, the disclosure of SEQ ID NO:1 does not provide an adequate description of the claimed genus.

Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO:1, 2) partial structure of DNAs that are capable of being cloned to SEQ ID NO:1, 3) the breadth of the claim as reading on genes yet to be discovered in addition to numerous splice variants and cDNAs, 4) the lack of correlation between the structure and the function of the 3' end fragment and/or gene; in view of the level of knowledge and skill in the art, one skilled in the art would

not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise a DNA sequence comprising SEQ ID NO:1 and therefore the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001.

Response to Arguments:

Applicants traverse the rejection under 35 USC 112 first paragraph based on a lack of written description. The examiner acknowledges applicants citation of the federal register, Vol. 66, No.4, in which it is stated that "what is conventional or well known to one or ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly…."(Pg. 9). However, the examiner maintains that the adequate written description requirement was not present as the specification as originally filed did not provide conventional, well known to one of ordinary skill in the art, or any other evidence causing the examiner to assert that the inventor was in possession of the claimed invention at the time of filing. On page 31 of the specification, "SEQ ID NO:1(31.2) which is basically a 3' end region of the gene" is described. However the description of the claim written with the open-language "comprising" is absent from the specification as previously written in the above rejection. The applicant is encouraged to use closed language terms such as "consisting of" in order to attempt to meet the written description requirement.

THE FOLLOWING NEW REJECTIONS ARE NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 37 is indefinite over the recitation of "capable of being cloned" as it is not clear what criteria applicant is considering in their determination of capability. It is not clear how the polynucleotide sequence's capabilities differ from other sequence's capabilities when it comes to cloning full-length cDNA. It is not clear under what conditions can the sequence be capable, under what conditions it cannot, and what attributes of the sequence make it so capable. Applicant should clarify their intentions for their use of "capable of being cloned".

B. Claim 38 is indefinite over the recitation of "capable of being cloned" as it is not clear what criteria applicant is considering in their determination of capability. It is not clear how the polynucleotide sequence's capabilities differ from other sequence's capabilities when it comes to cloning full-length genomic DNA. It is not clear under what conditions the sequence can be capable, under what conditions it cannot, and what attributes of the sequence make it so capable. Applicant should clarify their intentions for their use of "capable of being cloned".

C. Claim 39 is indefinite over the recitation of "capable of being cloned" as it is not clear what criteria applicant is considering in their determination of capability. It is not clear how the polynucleotide sequence's capabilities differ from other sequence's capabilities when it

comes to cloning a sequence to a promoter sequence or a regulatory sequence. It is not clear under what conditions can the sequence be capable, under what conditions it cannot, and what attributes of the sequence make it so capable. Furthermore, it is unclear in this claim the different capabilities had by the same sequences in its ability to be cloned to a promoter sequence or regulatory sequence as the sense of cloning is different from that implied in cloning to full length cDNA or genomic DNA. Applicant should clarify their intentions for their use of "capable of being cloned".

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number until 1/13/2004 is (703) 306-0284 and 1/14/2004 and after will be (571)272-0748. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

11/26/2003

CARLA J. MYERS
PRIMARY EXAMINER